Remarks

Courtesies extended to Applicants' representative in the personal interview held on May 18, 2004, are acknowledged with appreciation.

As discussed at the personal interview, the present invention provides novel methods of screening compounds for binding to novel receptors that are members of a new superfamily of receptor proteins having three distinct domains: an extracellular, ligand-binding domain; a hydrophobic, trans-membrane domain; and an intracellular, receptor domain having serine kinase-like activity. In preferred embodiments, invention receptors have binding affinity for activin. Compounds identified by invention methods are useful, for example, for the therapeutic management of carcinogenesis, wound healing, and disorders of the immune, reproductive, or central nervous systems.

Initially, Applicants respectfully disagree with the Examiner's designation of the present Office Action as a Final Office Action on the grounds that "Applicant's amendment necessitated the new ground(s) of rejection presented" (see Office Action, at page 12, lines 9-10). The new ground of rejection is an enablement rejection under 35 U.S.C. § 112, first paragraph. Applicants respectfully submit that in the Response submitted on September 26, 2003, claim 11 was amended to *further define* the receptor employed in the claimed method as a vertebrate activin receptor, and also to add reference to specific nucleotide sequence. This amendment provided further clarification of the receptor utilized in the claimed methods, and could not necessitate a new enablement rejection. Accordingly, Applicants respectfully submit that the finality of this Office Action is premature, and request reconsideration and withdrawal of the finality of this Office Action.

Claims 11 and 18-36 were pending before this communication. Claims 11 and 27 have been amended and new claims 37 and 38 have been added to define Applicants' invention with greater particularity. These amendments add no new matter as they are fully supported by the specification and the original claims. In addition, the total number of claims has been reduced

since claims 21-24 and 31-34 have been cancelled without prejudice. Applicants respectfully submit that the amendments presented herein place the application in condition for allowance or, at a minimum, reduce the issues for appeal. Accordingly, entry of the amendments is respectfully requested.

Accordingly, claims 11, 18-20, 25-30 and 35-38 are currently pending in this application. The present status of all claims in the application, and amendments thereto are provided in the listing of claims presented herein beginning on page 2.

The rejection of claims 11, 21 and 27-34 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for the scope of the claims, is respectfully traversed. Applicants respectfully submit that a person skilled in the art could readily make and use the claimed invention commensurate in scope with the claims.

However, in efforts to advance prosecution and reduce the issues, claims 11 and 27 have been amended herein to refer to the polypeptides employed therein using both structural and functional requirements. Specifically, the vertebrate activin receptor of claim 11 "has binding affinity for activin" (functional) and "has at least about 80% amino acid identity with SEQ ID NO:16" (structural). The soluble polypeptide of claim 27 "has binding affinity for activin" (functional) and "has at least about 80% amino acid identity with amino acid residues 20-134 of SEQ ID NO:16" (structural). In addition, the activin receptor of new claim 37 "has binding affinity for activin" (functional) and "is encoded by nucleotides having at least 90% sequence homology with respect to the contiguous nucleotide sequence of nucleotides 128-1609 of SEQ ID NO:15" (structural).

The present amendments are in accordance with the discussion at the personal interview, and the Examiner's suggestion to "eliminate the hybridization language in the claims and to recite a percent identify with a specific functional limitation" (see Interview Summary, Continuation sheet (PTOL-413) at lines 5-6). Moreover, the Examiner has acknowledged that

the specification is "enabling for a screening method of using a vertebrate activin receptor set forth in SEQ ID NO:2, 4, or 16" (see Office Action, at page 2, lines 19-20).

Accordingly, Applicants respectfully request reconsideration and withdrawal of this enablement rejection of claims 11, 21 and 27-34 under 35 U.S.C. § 112, first paragraph.

The rejection of claims 11, 21 and 27-34 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, is respectfully traversed. Applicants respectfully submit that a person skilled in the art would have no reason to doubt Applicants' possession of the claimed methods employing the respective peptides therein.

However, in efforts to advance prosecution and reduce the issues, claims 11 and 27 have been amended herein as described above to refer to the polypeptides employed therein using both structural and functional limitations. Accordingly, Applicants respectfully request reconsideration and withdrawal of this written description rejection of claims 11, 21 and 27-34 under 35 U.S.C. § 112, first paragraph.

The rejection of claims 11 and 18-36 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, is respectfully traversed. Applicants respectfully submit that the present claims contemplate screening a collection of compounds for those compounds having the ability to bind to receptors of the activin/TGF-β superfamily. There is no requirement for a compound to bind to every receptor of the activin/TGF-β superfamily. The Examiner's assertion that "a compound that binds to an activin receptor does not necessarily bind to a TGF-β receptor" (see Office Action, at paragraph bridging pages 9-10) would appear to reflect that the Examiner is requiring a compound to bind to every receptor of the superfamily. As such, the Examiner is inappropriately imposing an unclaimed requirement into the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 11 and 18-36 under 35 U.S.C. § 112, second paragraph.

The rejection of claims 11, 21, 27 and 31 under 35 U.S.C. § 102(b), as allegedly being anticipated by Kondo *et al., Biochem. Biophys. Res. Commun.* **161**:1267-1272, 1989 (hereinafter referred to as "Kondo"), is respectfully traversed. The present claims, as defined by amended claim 11, require the use, in the claimed methods, of a specific vertebrate activin receptor with at least 80% amino acid identity with SEQ ID NO:16. In contrast, Kondo merely discloses the binding of activinA to an uncharacterized receptor in cultured cells. Therefore, Kondo does not teach or suggest a method for screening a collection of compounds employing a vertebrate activin receptor as claimed. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 11, 21, 27 and 31 under 35 U.S.C. § 102(b).

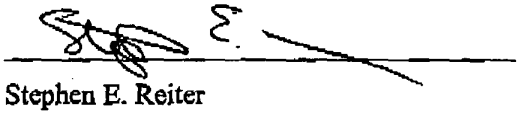
The objection to claim 11 as allegedly encompassing non-elected subject matter is respectfully traversed. The method of amended claim 11 comprises employing a vertebrate activin receptor having at least 80% amino acid identity with SEQ ID NO:16 in a competitive binding assay. Thus, the claim, as amended, only embraces elected subject matter. Accordingly, the objection has been rendered moot by the amendments submitted herewith.

Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: May 24, 2004



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